K120103

FEB - 3 2012

510(k) SUMMARY

Ranir, LLC's
Rest Assured Generation III Dental Protector

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: January 12, 2012

Name of Device and Name/Address of Sponsor

Rest Assured Generation III Dental Protector

Ranir, LLC
4701 East Paris Avenue SE
Grand Rapids, MI 49512
Phone: (616) 698-8880
Facsimile: (616) 656-7650

Common or Usual Name

Nightguard

Classification Name

Mouthguard, Over-the-Counter

Classification Product Code

OBR

Predicate Devices

Ranir, LLC's Rest Assured Generation II Dental Protector (K091792)
DenTek Oral Care, Inc.'s Night Guard (K063483)

Purpose of the Special 510(k) Notice

The Rest Assured Generation III is a modification to Ranir's Rest Assured Generation II Dental Protector (K091792).

The Rest Assured Generation III is the same device as Ranir's Rest Assured Generation II with the following minor differences: a reduction in the overall mass of the device, slight increase in arc width, additional impression material and base material, removal of sidewall material, addition of a small triangle fitting notch, and limited labeling changes.

Intended Use

The Rest Assured III is indicated for use for protection against bruxism or nighttime teeth grinding. The device is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Technological Characteristics

The Rest Assured III is a fully occlusive nightguard, fitted to the patient by the "boil and bite" method. Similarly, the predicate devices are fully occlusive nightguards fitted by the "boil and bite method"; therefore, the Rest Assured III is technologically similar to the predicate devices.

Substantial Equivalence

FDA cleared the claimed predicate devices, the Rest Assured II (K091792) and the DenTek NightGuard (K063483), for the reduction of damage to the teeth and the prevention of the noise associated with bruxing or grinding. In other words, the Rest Assured III has the same indications for use as the Rest Assured II and the DenTek NightGuard.

The Rest Assured III has very similar technological characteristics as the Rest Assured II, to which it is a modification, and to the DenTek NightGuard. All three devices are fully occlusive nightguards, which contain a hard occlusal base tray, overlaid with a softer, occlusal layer which contacts the patient's teeth and gingiva. In addition, the three devices are custom fitted by the user by the "boil and bite" method.

In sum, the Rest Assured III is as safe and effective as the predicate devices. The Rest Assured III has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between the Rest Assured III and the predicate devices raise no new questions of safety or effectiveness. Thus, the Rest Assured III is substantially equivalent.

Performance Testing

A risk analysis for the subject device was performed per ISO 14971 and ISO 7405 was adhered to in the evaluation of biocompatibility of device materials.

In addition, a third party testing laboratory tested the device to establish that the subject device is comparable to a legally marketed device. The third party laboratory verified that the subject device is comparable to a legally marketed predicate device.

Lastly, a user study was conducted to verify that the modifications to the device provided increased flexibility and ease in the fitting process. Ninety percent (90%) of the participants were pleased with the overall fitting process and fit their device correctly.

In sum, the above summarized testing confirm that the Rest Assured Generation III is substantially equivalent to the claimed predicate devices in intended use, device design, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ranir, LLC
C/O Mr. Gerard J. Prud'homme
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555 Thirteenth Street, N.W.
Washington, DC 20004

FEB - 3 2012

Re: K120103
Trade/Device Name: Rest Assured Generation III Dental Protector
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: OBR
Dated: January 12, 2012
Received: January 12, 2012

Dear Mr. Prud'homme:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120103

Device Name: Rest Assured Generation III Dental Protector

Indications for Use:

The Rest Assured Generation III Dental Protector is indicated for use for protection against bruxism or nighttime teeth grinding. The device is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Prescription Use ____ AND/OR Over-The-Counter Use _X_
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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